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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,729	12/21/2001	Jaap M. Middeldorp	9250-13DVCTDV	6359

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EXAMINER	
WOITACH, JOSEPH T	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 03/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/036,729	MIDDELDORP ET AL.	
	Examiner	Art Unit	
	Joseph T. Woitach	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-9,26,27 and 32-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) *7,8,26,27 and 32-34* is/are allowed.

6)☒ Claim(s) *6 and 9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 December 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 08/031,148.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 12, 2005 has been entered.

DETAILED ACTION

This application filed December 21, 2001, is a DIV of 09/205,169, filed 12/04/1998, now US Pat 6,365,717, which is a CON of 08/415,838, filed 04/03/1995, now US Pat 6,008,327, which is a DIV of 08/031,148, filed 03/12/1993, now US Pat 5,424,398.

Please note that the Examiner of record and art unit has changed. The Examiner of record is now Joseph T. Woitach and the group art unit is now 1632.

Applicants' amendment filed December 12, 2005 has been received and entered. Claims 1-5, 10-25, 28-31 have been canceled. Claims 6-8, 32-34 have been amended. Claims 6-9, 26, 27 and 32-34 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6-9, 26-27, 30, and 31rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn.

Applicants note the amendments to the claims, providing additional art for what one would accept as an "epitope" (pages 5-6), and summarize how this clearly defines the claim (bottom of page 6 to page 7). Pointing to the numerous examples provided in the specification, Applicants argue that the amendments to the claims have addressed the basis of the rejection. See Applicants' amendment, pages 5-7, Section II A. Applicants' arguments have been fully considered and found persuasive in part.

Initially, it is noted that for claims 7, 8, 26, 27, 32-34, each have been amended and the claims now encompass fragments of specific SEQ ID NOs providing a clear description of the invention.

At issue in the prior rejection is not fragments of VCA-p18 or –p40, but rather as represented in section 6(b) as a *functional variant* of said peptide described in a, wherein said variant is immunochemically reactive with antibodies to the EBV virus VCA-p18 or VCA-p40 proteins, and the fact that without any specific SEQ ID NO, that simply reciting p18 or p40 would encompass all possible variants as well. Setting forth in the claim that it is immunoreactive with antibodies to VCA-p18 or VCA-p40 proteins provides at best a circular definition in that any alteration/variation to p18 or p40 can be made and if an antibody can be made to this, it would fall into the breadth of the claim. Given that there is no specific function set forth, or different a variant can or can not be, the claims can reasonably interpreted to be effectively any nucleic sequence. In this case, a functional variant can reasonably be interpreted

to encompass another protein of EBV that would provide a source of antigen to EBV. With respect to claims 6 and 9, Examiner has evaluated the breadth of the claim in light of the general disclosure of the specification, and would agree that the specification provides for the literal support of the invention as claimed, and is not an issue of 35 USC 112, first paragraph. Rather, at issue is a reasonable interpretation of the claim embodiments. It is noted that every possible species encompassed by the claims are not provided in the present specification, however the conceptual nature and the breadth of the invention as claimed is provided.

Claims 32-34 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn.

The amendments to the claims to recite "the nucleic acid sequence of SEQ ID NO"s and deleting "at least" has addressed the basis of the rejection. Further, Examiner agrees that the specification broadly supports this in its reduction to practice of multiple overlapping 12mers for both VCA-p18 and p40, and their use in determining immunogenic properties.

Claims rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for amplification and detection of EBV virus nucleic acid sequence in a sample involving primer mediated amplification, wherein said primer is complementary to a region from SEQ ID NO: 1 and 3, does not reasonably provide enablement for the method of amplification and detection of EBV virus nucleic acid sequence is withdrawn.

The cancellation of claims has rendered the rejection moot.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6 and 9 stand rejected under 35 U.S.C. 102(b) as being anticipated by Ambinder et al. (Abstracts from Annual Meeting American Society of Microbiology, 1989, 89 Meet., 111, cited previously).

Applicants argue that the interpretation of the claims is not reasonable, and that the cells of the cited references are infected with a latent EBV, and would not produce the proteins set forth in the claims. See Applicants' amendment, pages 9-10. Applicants arguments have been fully considered, but not found persuasive.

Examiner appreciates that a single amino acid will not by itself serve as an epitope, and that the cells of the cited reference may or may not produce proteins recited in the claims. However, at issue is what is being claimed, a nucleic acid sequence-not a protein, and the breadth of the claim, in particular "a functional variant" set forth in 6(b). It is appreciated that there is an attempt to define the structure of the "variant" by the ability of an antibody to react with an antibody that reacts with VCA-p18 or –p40, however this appears to be a circular limitation. Claim 6(a) only sets forth VCA-p18/p40 and as a name would reasonable be interpreted to encompass all variants of these proteins that one in the art would term to be VCAp18/p40. Further, there is no specific antibody set forth in the claims, nor defined in the specification that would limit the interpretation of the claim to any one particular sequence.

Given that what is meant by a "functional variant" is not specifically set forth in the claim except for the ability to be bound by an antibody, nor is it defined in the specification, therefore a reasonable interpretation would be effectively any protein from VCA. In this case, absent evidence to the contrary, the nucleic acid disclosed by Ambinder et al., which is different in sequences (thus a variant), would meet the limitations of the claims as broadly set forth.

According to *In re Best* 195 USPQ 430, 1997, the court stated that, "Patent Office can require applicant to prove that prior art products do not necessarily or inherently posses characteristics of his claimed product wherein claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes; burden of proof is on applicant" (pp. 430). The nucleic acid encoded by Ambinder *et al.* is structurally different (thus, a variant). Whether the protein encoded by the nucleic acid of Ambinder *et al.* is not determinable as the PTO does not have the facility to conduct experiments. It is determined that the burden has been shifted to Applicants to provide contradicting evidence.

Therefore, Ambinder *et al.* would anticipate the invention as claimed.

Conclusion

Claims 7, 8, 26, 27 and 32-34 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach